510(k) Summary

Submitter Information:

K100920

Submitter: SeQual Technologies Co., Ltd
6F-7, No.136, Sec.3, Ren-ai Rd.
10657, Taipei, Taiwan (R.O.C.)

NOV 29 2010

Contact: Cearo Huang, Director, Engineering & Research Division

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Date of Summary: February 5, 2010

Device Name:

Proprietary Name: MESA II Oxygen Concentrator, Model T2000 Series
Common Name: Oxygen Concentrator
Classification of Device: Generator, Oxygen, Portable as per 21 CFR 868.5440

Predicate Device Equivalence:

SeQual Technologies Co., Ltd is claiming substantial equivalence to the following legally marketed predicate devices:
K042262 – INTEGRA E-Z Oxygen Concentrators Model 6323OM-10
K043006 – Respironics Millennium M10 Oxygen Concentrator

Description of Device:

The SeQual Model T2000 Series, MESA II Oxygen Concentrator, is a 0.5 to 10.0 Liter per minute (LPM) continuous flow pressure swing adsorption (PSA) type system that produces oxygen.

The SeQual Model T2000 Series, MESA II Oxygen Concentrator, consists of pneumatic and electrical components. The system has inlet filtration, air compressors, heat exchanger, and Synthetic Zeolite molecular sieve beds with a rotary valve, outlet filtration, electronic flow control and audible / visual alarms.

Predicate Product Comparison Table:

Device Name	MESA II (10LPM)	INTEGRA E-Z (10LPM)	RESPIRONICS M10 Concentrator
Oxygen Generating System	12-Column Pressure Swing Adsorption	12-Column Pressure Swing Adsorption	Time Cycle/Pressure Swing Adsorption
Valve Type	Single Rotary Valve Driven by Gear Motor	Single Rotary Valve Driven by Gear Motor	Exclusive Rotary Valve System
Compressor	Thomas 2660CE48	Thomas 2660CE48	Thomas 2660CE54
Filtration	Glass Microfiber, HEPA, 0.3μm at Outle	Glass Microfiber, HEPA, 0.3μm at Outlet	Final Bacteria Filter, HEPA
Control and Communication System	PCBA/Membrane Switch/RS-232***	PCBA/Membrane Switch	Communication Port/Compensated Flow Meter
Equipment Class and Type	Class II / BF	Class II / BF	Class II / B
EMC Compliance	60601-1-2	60601-1-2	60601-1-2
Dimension			
Height (mm)	580	660	686
Width (mm)	400	370	483
Depth (mm)	500	500	330
Volume (L)	116.0	122.1	109.3
Weight (kg)	23	26.0	24.0
Oxygen Concentration (OC)*			
8-10 LPM	91 ± 3	91 ± 3	92 ± 4
3-7 LPM	94 ± 3	94 ± 3	94 ± 2
1-2 LPM	94 ± 3	94 ± 3	92 ± 4
Operation Condition			
Flow Rate (LPM)	0.5 ~ 10.0 LPM by 0.5 LPM Increment	0.5 ~ 10.0 LPM by 0.5 LPM Increment	1.0 ~ 10.0 LPM
Outlet Pressure (psig)	5.0 ~ 10.0	7.5 ~ 11.0	2.7
Electrical Input	115VAC +10% ~ -15% 60Hz	115VAC +10% ~ -15% 60Hz ± 3Hz	115VAC +10% ~ -15% 60HZ
Oxygen Concentration Monitor	PRO-WAVE Model GAS400**	PRO-WAVE Model GAS400**	Oxygen Percentage Indicator, OPI,
Alarms	Power/Compressor Malfunction/Abnormal Flowrate /Low OC/Over Temperature	Power/Compressor Malfunction/Abnormal Flowrate /Low OC/Over Temperature	High/low pressure, low oxygen, power failure, no oxygen flow

Manufacturer	SeQual Technologies Co., Ltd.	SeQual Technologies Inc.	Respironics Inc.
510(k) No.	N/A	K042262	K043006
Intended Use	The SeQual MESA II Oxygen Concentrator is intended to provide supplemental oxygen. It is not intended for life supporting, or life sustaining applications nor does it provide any patient monitoring capabilities.	The SeQual Integra Oxygen Concentrator is intended to provide supplemental oxygen. It is not intended for life supporting, or life sustaining applications nor does it provide any patient monitoring capabilities.	The Respironics M10 Concentrator is intended to provide supplemental oxygen to persons requiring low flow oxygen therapy. The device is not intended to be life supporting nor life sustaining.
Interface	A standard discrete logic and analog circuitry (PCBA system) is used for all monitoring and alarm functions.	A standard discrete logic and analog circuitry (PCBA system) is used for all monitoring and alarm functions.	Oxygen Percentage Indicator(OPI) ultronically measures the oxygen output as purity indication.

*: OC represents oxygen concentration.

**: Where equipped. Measure the output as an oxygen concentration monitor.

***: Where equipped. RS-232 communication channel provide technician detail system information from PCBA.

Intended Use:

The SeQual Model T2000 Series, MESA II Oxygen Concentrator, is intended for the administration of supplemental oxygen up to 10 LPM. The device is not intended for life support nor does it provide any patient monitoring capabilities.
The device has no contraindications.

Technological Characteristics:

The SeQual Model T2000 Series, MESA II Oxygen Concentrator, operates comparably to the listed predicate devices. The technology employed to generate the oxygen is well established, and therefore, raise no new questions of safety and effectiveness.

Performance Data:

Results of the oxygen concentraton testing to ISO 8359 and ASTM 1464 standards confirm the device meets specifications and is substantially equivalent to the predicate devices.

Conclusion:

Based on the design, performance specifications, tests and intended use, the SeQual Model T2000 Series, MESA II Oxygen Concentrator is substantially equivalent to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Cearo Huang
Director, Engineering & Research Division
SeQual Technologies Company, Limited
6F-7, No.136, Sec.3, Ren-ai Rd..
10657, Taipei, Taiwan (R.O.C.)

NOV 2 9 2010

Re: K100920
Trade/Device Name: MESA II Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Oxygen Concentrator
Regulatory Class: II
Product Code: CAW
Dated: November 10, 2010
Received: November 12, 2010

Dear Mr. Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100920

TATUNG SEQUAL

Indications for Use

510(k) Number (if known): NOV 2 9 2010

Device Name: MESA II Oxygen Concentrator

Indications For Use:

The MESA II Oxygen Concentrator (Model No.: T2000 Series) is intended to provide supplemental oxygen. It is not intended for life supporting, or life sustaining applications nor does it provide any patient monitoring capabilities.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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